

REMARKS

The applicant respectfully requests reconsideration of claims 1-3, 5-8, 14-15, 17, and 25 in view of the foregoing amendment, and consideration of new claims 52-75. Claims 4, 9-13, 16, 18-24 and 26-51 are cancelled without prejudice, primarily but not entirely as a result of the earlier election.

A. The specification is subject to an objection for lack of a reference to Figure 4a in the “In the Drawings” section. The foregoing amendment includes an amendment to the specification at page 8, adding a paragraph describing Figure 4a.

B. Figure 2 of the drawings is subject to an objection, due to the lack of an indication that Figure 2 illustrates prior art. The present amendment includes a replacement sheet (Figures 1-3) in which the legend “(PRIOR ART)” is added to Figure 2.

C. Claims 1-4, 8, 14, 15, 17, 25-27 and 29 stand rejected under 35 U.S.C. § 102(e), as allegedly anticipated by U.S. Publication No. US 2001/0041930 A1 (Globerman, et al.).

The Globerman application discloses a stent having varying degrees of flexibility or stiffness. Figure 2 shows a stent 1 with sections 5, 7, 9, 11, 13 and 15 in an axial sequence (from bottom to top as viewed in Figure 2). End sections 5 and 15 are the least rigid; inward or central sections 9 and 11 are the most rigid; and sections 7 and 13 have an intermediate rigidity. Figure 3 shows a balloon-expandable stent with cross members 35 that are “more rigid toward the longitudinal center of stent 31 and less rigid toward the ends.” See paragraph [0015].

Claim 1 defines a prosthesis including a tubular structure in which at least one flexible strand is formed to provide a plurality of discrete first tubular segments and a plurality of discrete second tubular segments in an alternating sequence. The first and second tubular segments have respective first and second nominal diameters. The tubular structure is radially compressible against an elastic restoring force to a predetermined diameter. When the tubular structure is compressed into the predetermined diameter, the first tubular segments have first axial stiffness levels and first radial force levels, and the second tubular segments have second axial stiffness levels and second radial force levels. The first axial stiffness levels are higher than the second axial stiffness levels, whereby the second tubular segments are adapted to more readily conform to the curvature of a body lumen in which the tubular structure is deployed.

Thus amended, claim 1 defines a tubular structure in which an alternating sequence of tubular segments includes at least two first segments of relatively high axial stiffness and at least two second tubular segments of relatively low axial stiffness. This arrangement is particularly well suited to tailoring the tubular structure to support either more gradually curved or more severely curved regions of a curved body lumen (specification page 3, lines 11-14). As noted in the specification at page 10, beginning with line 10, stent segments 22 with a higher axial or longitudinal stiffness mitigate axial for shortening of the stent as it radially expands. Meanwhile, stent segments 24 have a higher axial flexibility, and thus more readily conform to the curvature of the body lumen, in this case colon 18. Thus, sections with higher axial flexibility can be aligned with the sharper or more severe curves in the body lumen.

Each first tubular segment has an axial stiffness level higher than the axial stiffness level of any of the second segments. Each second segment has an axial stiffness level lower than that of any of the first tubular segments.

The claimed arrangement is not taught by Globerman, even though the Globerman design includes sections that have different stiffness levels and form a sequence. This is because the sequence, in each case, involves a lowest stiffness level at the ends of the stent and increases in both directions toward the center where the maximum stiffness sections reside. This arrangement is well suited for Globerman's purpose, which is to provide "significant durability for bending at the exact place where the durability is required, that is, at the middle of the stent." See paragraph [0004].

This arrangement, however, does not teach or suggest the prosthesis of claim 1. With reference to Globerman's Figure 2 version, a sequence of six stent sections is shown. However, the sequence fails to teach the sequence defined in claim 1, in which the relatively high axial stiffness first segments alternate with the relatively low stiffness second segments. Claim 1 contemplates a minimum of four tubular segments, two first segments and two second segments.

Regardless of which four segments in Globerman's stent 1 (Figure 2) are chosen for its sequence, the chosen sequence cannot satisfy the condition of alternating higher and lower axial stiffness levels defined in claim 1.

Globerman's stent 31 (Figure 3) is not discussed in sufficient detail to teach the specific number of segments and different stiffness levels involved. However, as noted above, the cross

members are more rigid toward the longitudinal center and less rigid toward the ends. Thus, as in stent 1, stiffness values are lowest at the ends, and increase in the direction toward the center, where the sections of maximum stiffness reside.

It is well settled that anticipation requires, in the allegedly anticipatory reference, the disclosure of each and every element of the claim. Globerman fails to teach or suggest the claimed alternating arrangement of tubular segments with relatively high and relatively low axial stiffness levels, and thus fails to anticipate the prosthesis defined in claim 1.

Claims 2-3, 8, 14-15 and 17 depend on claim 1 and are patentable for the reasons given in support of claim 1. For the following further reasons, the Globerman application fails to anticipate certain dependent claims, as follows:

1. Claims 2 and 3, for the failure to teach or suggest tubular segments with different axial stiffness levels in which all of the first stiffness levels, or all of the second stiffness levels, are substantially the same; and
2. Claim 14, for the failure to teach or suggest a tubular structure consisting essentially of the first and second tubular segments.

Claim 25 is drawn to a prosthesis with a body insertable tubular wall incorporating a plurality of first tubular wall segments and a plurality of second tubular wall segments. When the first and second wall segments are radially compressed to a predetermined diameter, the first tubular wall segments have relatively high first axial stiffness levels and the second tubular wall segments have second axial stiffness levels lower than the first axial stiffness levels.

Accordingly, it is submitted that claim 25 is patentable over the Globerman application for the reasons given in support of claim 1.

Claims 26-27 and 29 have been cancelled.

D. Claims 25 and 28-30 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,836,966 (St. Germain).

The St. Germain patent discloses stents with a radial force that varies in the axial direction along the stent. In one embodiment, the force is greater in the center and less at the ends, e.g. the stent shown in Figure 7 with a radial force plot like that in Figure 5. In another

embodiment, the radial force increases from one end to the other, as in stents having the plot of radial force shown in Figure 6.

As compared to Globerman, St. Germain while focused upon radial force discloses a similar force profile (maximum at the stent center, minimum at each end), and discloses an additional force profile that increases axially from one end to the other. The added profile (always increasing or always decreasing, depending on the direction), like the profile taught in both Globerman and St. Germain, fails to teach or suggest the sequence defined in claim 25, i.e. alternating segments of relatively high and relatively low axial stiffness.

Accordingly, claim 25 is patentable over the St. Germain patent, for the same reasons that is patentable over the Globerman application.

Claims 28-30 have been cancelled.

E. Claims 1 and 5 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by EP 0 880 948 A1 (Thompson, et al.).

The Thompson reference discloses a stent-graft (e.g. Figure 11) with an upstream section 730, a downstream section 734, and a branch section 732 between the upstream and downstream sections. Thompson teaches that the upstream and/or downstream sections can be varied to change the amount of anchoring support being provided by these sections.

Even assuming that sections 730 and 734 are “varied” to change the axial stiffness as well as the anchoring support (anchoring support is a function of radial force, not axial stiffness), the disclosure in Thompson, like the disclosures of Globerman and St. Germain, fails to teach or suggest the claimed sequence of first and second tubular segments, respectively with relatively high and relatively low axial stiffness levels, in an alternating arrangement.

Accordingly, claim 1 is patentable over the Thompson reference.

F. Claims 6, 7, and 10 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 0 880 948 A1 (Thompson, et al) in view of U.S. Patent No. 5,836,966 (St. Germain).

Claim 6 further defines the prosthesis of claims 1 and 5 in that the second strand crossing angle is larger than the first strand crossing angle. According to claim 7, the crossing angles are substantially the same. In connection with this rejection, it is contended in the present action that

St. Germain teaches stents having various stiffness levels due to differentiation in crossing angle. Accepting this contention as correct arguendo, the combination of Thompson and St. Germain nonetheless fails to teach the prosthesis defined in claim 1, upon which claims 6 and 7 depend. More particularly, as neither Thompson nor St. Germain teaches the sequence of alternating tubular segments of high and low axial stiffnesses defined in claim 1, their combination likewise fails to teach this arrangement.

Accordingly, it is submitted that claims 6 and 7 are patentable over the Thompson/St. Germain combination.

Claim 10 has been cancelled.

New claims 52-75 depend on claim 25 and are allowable along with claim 25.

To summarize, it is submitted that claims 1-3, 5-8, 14-15, 17, and 25 in view of the present amendment, and new claims 52-75, incorporate subject matter patentable over the prior art of record. An early and favorable action allowing these claims is respectfully requested.

Respectfully submitted,

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Dated: November 24, 2004

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CERTIFICATE OF MAILING

Pursuant to 37 CFR 1.8, I hereby certify that this Amendment Pursuant to 37 C.F.R. 1.116 in Application Serial No. 10/038,640 is being deposited with the U.S. Postal Service by first class mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of deposit indicated below.

Date of Deposit: November 24, 2004



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